PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Bruno CRIERE et al.

Serial No.: 10/030,262 Group Art Unit: 1615

Filed: April 17, 2002 Examiner: Channavajjala, L. S.

For: PHARMACEUTICAL COMPOSITION CONTAINING FENOFIBRATE AND THE PREPARATION METHOD

SECOND DECLARATION OF GEORGE BOBOTAS, Ph.D., UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

I, George Bobotas, Ph.D., hereby declare and affirm that:

1. I am the same person that submitted a Declaration dated October 21, 2005 (October 21st Declaration or "Bobotas I") in support of the referenced patent application.
2. It is my understanding that the Examiner has requested clarification with respect to the composition of the test formulations described in the October 21st Declaration.
3. In my October 21st Declaration, I presented the results of three studies: A, B and C. Studies A and B assessed the relative bioavailability of 130 mg ANTARA® fenofibrate capsules of the invention versus 200 mg TRICOR® fenofibrate capsules. Study C assessed the relative bioavailability of 120 mg and 144 mg fenofibrate capsules of the invention versus 160 mg TRICOR® fenofibrate tablets.

Fenofibrate Capsules of the Invention

4. The 120 mg, 130 mg and 144 mg fenofibrate capsules of the invention utilized in Studies A, B, and C, each contained granules of the same composition. The granules are 64% by weight fenofibrate, relative to the weight of the granules; and 12% by weight binding cellulose derivative, relative to the weight of the granules.

200 mg TRICOR® Fenofibrate Capsules

5. The composition of the 200 mg TRICOR® fenofibrate capsules is described in the product insert (Attachment A, the first page of the product insert for 200 mg TRICOR® fenofibrate capsules), and in U.S. Patent No. 4,895,726 (Attachment B).[1] According to the product insert, 200 mg TRICOR® fenofibrate capsules contain the following inactive ingredients: crospovidone (i.e., crosslinked polyvinyl pyrrolidone), iron oxide, lactose, magnesium stearate, pregelatinized starch, sodium lauryl sulfate and titanium dioxide.
6. None of the ingredients utilized in the 200 mg TRICOR® fenofibrate capsules are described as binders in the Curtet ('726) patent.
7. I supervised an analysis of the 200 mg TRICOR® fenofibrate capsules to ascertain the weight percentage of fenofibrate in the formulation. 10 capsules (Lot # 727552E21) were opened and the contents were weighed. Dividing this amount by the number of capsules gave the average weight of the formulation in each capsule. The average weight of the formulation in each capsule was 343 mg. Thus, assuming that each capsule contained 200 mg fenofibrate, the formulation of the 200 mg TRICOR® fenofibrate capsules is about 58% fenofibrate by weight, relative to the weight of the formulation.

---

[1] *See, Bobotas I,* fn. 2 (the Curtet ('726) patent is listed by the distributor of TRICOR® in FDA's Orange Book as covering the product).

160 mg TRICOR® Fenofibrate Tablets

8. The composition of the 160 mg TRICOR® fenofibrate tablets is described in the product insert (Attachment C, the first page of the product insert for 160 mg TRICOR® fenofibrate tablets), and in U.S. Patent No. 6,074,670 (Attachment D).[2] According to the product insert, 160 mg TRICOR® fenofibrate tablets contain the following inactive ingredients: colloidal silicon dioxide, crospovidone, lactose monohydrate, lecithin, microcrystalline cellulose, polyvinyl alcohol, povidone (i.e., polyvinyl pyrrolidone), sodium lauryl sulfate, sodium stearyl fumarate, talc, titanium dioxide and xanthan gum.
9. I supervised an analysis of the 160 mg TRICOR® fenofibrate tablets to ascertain the weight percentage of fenofibrate in the formulation. 90 tablets (Lot # 02-8333R1) were weighed. Dividing this amount by the number of tablets gave the average weight of each tablet. The average weight of each tablet was 712 mg. Thus, assuming that each tablet contained 160 mg fenofibrate, each 160 mg TRICOR® fenofibrate tablet contains 23% fenofibrate by weight, relative to the weight of the tablet.

[2] *See, Bobotas I*, fn. 3 (the Stamm ('670) patent is listed by the distributor of TRICOR® in FDA's Orange Book as covering the product).

I, George Bobotas, Ph.D., hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent(s) issuing therefrom.

Date: 2/14/06

George Bobotas, Ph.D.

George Bobotas, Ph.D.